UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,491	12/13/2001	Roberto Villa	9615 V/vmf	4463

466 7590 06/09/2003

YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 06/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,491	VILLA ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 04/29/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franco et al. GB 2 245 492 A.

Franco teaches pharmaceutical dosage form comprising active a core; a coating layer comprises hydrophobic material having melting point from 50-90°C, surfactant, and water-soluble film forming material; and an enteric coating layer (see abstract and page 13). The hydrophobic coating material can be wax, hydrogenated castor oil, fatty acid esters, and mono-, di-, or tri-glycerides (page 7, lines 24 through column 8, lines 1-15). The water-soluble film forming material can be polymer or copolymer of acrylic or methacrylic acid, cellulose or cellulose derivatives (page 8, lines 24-30). The active agent used in the core can be selected from a variety of drugs, including mesalamine (page 10). The enteric coating or gastro-resistant coating material can be selected from methacrylic acid, methacrylic acid ester copolymer, cellulose phthalate, or polyvinyl acetate phthalate (page 12, lines 13-26). The process of preparing the dosage form is

disclosed in pages 10-12, and the examples). The composition can be in tablet, granule or capsule form (id).

It is noted that Franco teaches the use of surfactant in addition to the hydrophobic and the film-forming materials. While applicant's generic claim recites the transitional phrase "consisting of" to exclude other components in the lipophilic matrix, applicant's specification includes (discloses) the use of surfactant, *e.g.*, sodium starch glycolate, and magnesium stearate (examples). Furthermore, applicant's generic claim recites "an inner lipophilic matrix consisting of *substances*". It is the position of the examiner that the phrase "substances" allows the present of substance, including surfactant. Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation optimize Franco's dosage form with the expectation of at least similar result, because Franco teaches the advantageous results in the use of controlled release oral dosage form useful for releasing of drug in the colon.

Response to Arguments

Applicant's arguments filed 04/29/03 have been fully considered but they are not persuasive.

Claims 1-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franco et al. GB 2 245 492 A.

Applicant argues that Franco teaches a composition based on a reservoir, wherein the active ingredient is confined within a core and will release via the erosion of the outer coating. However, as to the present invention, the active ingredient is

dispersed in a lipophilic matrix. In response to applicant's argument that the reference does not show certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., the active ingredient is dispersed in a lipophilic matrix) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The limitation "active ingredient is at least *partly* inglobated" does not limit the claim to "active ingredient is dispersed in a lipophilic matrix" as alleged by the applicant. Furthermore, the term "controlled-release" does not limit the active ingredient in the core to release via the erosion of the outer coating. Although Franco is silent as to the teaching of "matrix", Franco teaches an oral pharmaceutical composition having controlled release property.

Applicant argues that the present invention does not require the use of surfactant. However, the term "substances" recites in applicant's generic claim permits the present of surfactant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600